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Pakistan

AGRICULTURAL BIOTECHNOLOGY ANNUAL

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Report Highlights:

Despite the lack of any approved GM crop in Pakistan, it is estimated that over 90 percent of the 2009 cotton crop was planted in illegal biotech varieties. Pakistan still does not have an official regulatory framework for agricultural biotechnology. However, significant progress is being made towards legalizing commercialization of biotech crops. Chinese seed companies have begun to make inroads in the Pakistani market. To date, scientists in Pakistan have not genetically engineered animals for any purpose.

Section I. Executive Summary:

The major U.S. agricultural biotechnology trade issues in Pakistan at this time are related to cotton, corn, the soybean sector and animal feed. There are no laws banning the import of products of biotechnology.

The Letter of Intent (LOI) signed between the GOP and Monsanto on May 14, 2008 is bearing fruit at a slow pace. Monsanto has received approval of the National Biosafety Committee (NBC) for field testing of Bt hybrid cotton. Pioneer Hi-bred and Bayer Crop Sciences Germany have also obtained approval for field testing of Bt cotton varieties.

However, delays in import approvals have resulted in no field trials to date.

Chinese seed companies and biotech firms entered the Pakistani seed market this year, entering into agreements with both public sector institutions and private companies.

Agricultural biotechnology in Pakistan is exclusively funded by the public sector. To date, no biotech crop has official approval for commercial use. However, 39 applications for experimental research and field trials have been approved by the National Biosafety Committee (NBC).

Pakistan ratified the Cartagena Protocol on Biosafety on May 31, 2009.

An official regulatory framework for agricultural biotechnology is still not in place; other related legislation, principally the Plant Breeders' Rights and Amendments to the Seed Act of 1976, are still awaiting promulgation.

To date, Pakistani scientists do not genetically engineer animals.

Section II. Biotechnology Trade and Production:

Commercial Production of Biotech Crops

The Government of Pakistan (GOP) has not officially approved any biotech seed for commercial production. That said, over 90 percent of the 2009 cotton crop, covering an area of about 8.5 million acres, is the product of unapproved Bt cottonseed.

Agricultural biotechnology is funded exclusively by the GOP through public sector research centers. These government institutions make arrangements with public and private sector seed companies to multiply their pre-basic seed or use it as source material for developing their own varieties. Private seed companies multiply the seed and make back crosses to develop new Bt cotton varieties.

In the recent past, widespread planting of illegal BT cotton had posed serious problems. The seed was not developed for Pakistan's agronomic conditions and, under certain conditions, had proven to be a poor performer. However, introgression into local germplasm has begun to pay dividends as farmers see crop improvements with the newer varieties.

Pakistan's harvested Bt cotton is utilized within the domestic textile industry as well as for the production of planting seed.

Biotechnology Crops under Development

A number of GM crops are under development in Pakistan by both public and private sector (national & foreign) seed companies. The GOP has invested over US\$ 20 million in biotechnology research and maintains a large network of 31 state-owned biotechnology research centers. At present, these facilities are mainly engaged in plant tissue culture; only six research centers are capable of performing DNA recombination to develop bioengineered plant varieties.

There are 39 cases of GM crops which were approved by the National Biosafety Committee (NBC) of the Environmental Protection Agency (EPA) for laboratory/green house and field testing. Two cases of commercial release

of GM cotton with single/double gene pertaining to public sector research organizations are in the pipeline with regulatory authorities.

Genetically modified crops in Pakistan

| GM Crop | Genetically Engineered traits | Stage |
|-----------|--|--|
| Cotton | Insect resistance with biotech and other genes, virus resistance, salinity tolerance, fiber modification, drought, herbicide tolerance | Experimental/field trials/ready for release. |
| Rice | Bacterial blight resistance, insect resistance | Field trial/ ready for release |
| Potato | Virus resistance, salt tolerance, insect resistance | Experimental |
| Sugarcane | Insect resistance | Experimental |
| Chickpea | Insect resistance, virus resistance | Experimental |
| Chilies | Virus resistance | Experimental |
| Tomato | Virus resistance, male sterility, salinity tolerance | Experimental |
| Cucurbits | Virus resistance | Experimental |
| Tobacco | Virus resistance | Experimental |
| Groundnut | Fungal resistance, herbicide tolerance | Experimental |

Imports of Crops and Products of Biotechnology

Pakistan imports large quantities of cotton from the United States and other sources. Much of this is Bt cotton.

Imports of biotech bulk commodities include feed corn, soybeans and soybean meal from the United States, Brazil, Argentina and other sources. Pakistan imports GM canola/rapeseed and sunflower seed from Canada and Australia.

U.S. soybean oil derived from biotech soybeans is also imported into Pakistan. Snack foods and other processed products containing U.S. soybean oil are imported into Pakistan without difficulty.

During the past year, the GOP - through the Pakistan Agricultural Research Council (PARC) - signed several MOU's with various Chinese seed companies. One ton of Bt cottonseed (hybrid and colored cotton) was imported and planted during the current cotton season. Other Chinese biotech crops under investigation include hybrid rice, corn, canola and certain vegetables.

Bt cotton from China and India has been imported by several Pakistani seed companies. Monsanto has begun the protocol process to import GM and hybrid cottonseed from India (Mahyco-Monsanto India). Pioneer Hi-bred is working with U.S. varieties and Bayer Crop Science Pakistan is in the process of importing hybrid Bt cottonseed from Bayer India.

Food Aid

Pakistan is a food aid recipient country. Since 2003, Pakistan has received soybean oil, wheat, non-fat dry milk and tallow from the United States under various USDA-funded assistance programs. U.S. soybean oil is generally derived from bioengineered soybeans.

There are no issues related to imports of GM food aid into Pakistan.

Non-U.S. Biotech Crops in Export Channels

Within the public sector, many biotech crops which have not passed through the U.S. regulatory system are being developed locally or with the collaboration of Chinese seed companies. These crops include cotton, rice, wheat, potatoes and peanuts.

Pakistan is a major exporter of raw cotton and cotton products to the United States and many other destinations. Cotton product exports include cotton yarn, cotton fabric and other items manufactured from cotton. Cotton textiles and apparel are major export items from Pakistan to the United States. These products could be derived from illegal Bt cotton grown in Pakistan or from bioengineered cotton imported from other trading partners.

Section IV. Biotechnology Policy: Regulatory Framework

While Pakistan still does not have an official biotechnology regulatory framework, an elaborate system to review products of genetic engineering is in place. Unfortunately, human resource and infrastructure capacity is sorely lacking.

The proposed regulatory guidelines are built upon on a three-tier system composed of the National Biosafety Committee (NBC); a Technical Advisory Committee (TAC); and Institutional Biosafety Committees (IBC).

The Secretary of the Ministry of Environment heads the NBC, and will be responsible for oversight of all laboratory work and field trials, as well as authorizing the commercial release of GM products. The three monitoring and implementing bodies will administer enforcement of the National Biosafety Guidelines. The IBC may make recommendations to the NBC regarding the awarding of exemptions for laboratory and fieldwork related to products of bioengineering. These recommendations will be accepted, and formal approval granted, if sufficient information and grounds exist to consider the risk as being minimal or non-existent. After permission for deregulation is granted by the NBC, approval can still be withdrawn provided sufficient technical data and other evidence later becomes available that warrants a review.

The Ministry of Food and Agriculture (MinFA) also has a role in regulating the production and release of genetically engineered crops. MinFA has developed Standard Operating Procedures for the handling of imports, approvals and environmental release of GM events. However, these procedures have yet to be promulgated.

Responsible Government Ministries/Institutes

The National Biosafety Committee (NBC) at the National Biosafety Directorate in the Ministry of Environment is responsible for all biosafety work related to biotechnology. There are nearly 20 members of the NBC from the Ministries of Environment, Science and Technology, Health, Agriculture, Education, the Pakistan Agriculture Research Council, the Pakistan Atomic Energy Commission, and representatives from the Provinces, Azad Jammu and Kashmir. The NBC discusses, evaluates and makes decisions regarding submissions from the Institutional Biosafety Committee (IBC) and/or the Technical Advisory Committee (TAC).

Pakistan's biotech research institutes, multinational firms and local companies marketing pesticides and seeds follow agricultural biotechnology issues closely. They monitor changes in the structure of the regulatory framework, the formation of biotechnology policy and the implementation of action plans and procedures.

The National Commission on Biotechnology (NCB) was established on November 30, 2001, with the purpose of

focusing on policy issues in the field of biotechnology. Unfortunately, this Commission is functioning on borrowed time as project funding has expired and the GOP has not shifted the NCB from project status to a regular institute. The NCB was designed to coordinate and serve as a focal point for the exchange of information with GOP Ministries and Agencies, as well as all international initiatives related to agricultural biotechnology. It has funded 34 domestic and international seminars and conferences on the commercialization of products of biotechnology at various universities and institutes. Regrettably, the NCB has so far been ineffective in gaining consensus in resolving Pakistan's major policy issues related to biotech intellectual property rights, plant breeder's rights and biosafety laws.

The Ministry of Food and Agriculture (MinFA) has taken the lead in public/private sector cooperation with Monsanto following the signing of a Letter of Intent (LOI) to expand collaboration in advanced transgenic technology.

The Government of the Punjab has also signed various MOU's with Chinese seed companies looking for cooperative arrangements in biotechnology to enhance agricultural production at the provincial level.

Unresolved Political Factors – IPR and Seed Policy

On the policy and legislative side, the Seed Act of 1976 Amendment and the Plant Breeders' Rights Bill are yet to be approved by Parliament. As these laws have now been returned to the Provincial Assemblies for their concurrence, timely promulgation is not anticipated.

The current Seed Act is outdated and limited to public sector seed companies only. Proposed amendments to the Seed Act would allow national centers which conduct research and development to transfer genetic material to private companies. Higher punitive measures and fines have been proposed to deter the illegal sale of seed.

The Plant Breeders' Rights (PBR) Bill would allow for the registration of varieties and the payment of royalties along the lines of the European system. Farmers would be allowed to exchange seed but could not sell the seed on a commercial basis.

The delay in seed and plant breeder legislation is perceived as a major impediment to investment in Pakistan by multinational seed companies. Reluctance in finalizing this legislation is due, in part, to the desire of Pakistan's research communities to remain autonomous. Moreover, potential investors do not believe that their proprietary rights will be fully protected under the current proposals. These fears have been heightened as Pakistan's Intellectual Property Organization (IPO) has recently suffered serious setbacks due to highly publicized mismanagement.

Approved Biotechnology Crops

To date, there is no biotechnology crop approved for cultivation in Pakistan, and there are no domestic biotech crops legally approved for food, processing animal feed in Pakistan.

However, 39 biotech events have been approved for experimental/greenhouse and field evaluation. Consequently, there is hope that domestic biotech crops will be legally approved for planting by Pakistan's farm community within the next year or two.

Field Testing of Biotechnology Crops

The National Biosafety Committee (NBC) has recently begun to allow field testing of biotechnology crops.

Six Bt cotton varieties are in their second year of field trials. A GM sugarcane variety suffered from frost damage and trials were abandoned. These public sector field trials are considered to be less rigorous than comparable private sector field trials.

Monsanto, Pioneer Hi-Bred and Bayer Crop Sciences were unable to begin field trials due to delays in import approvals for genetically modified seed from India.

In collaboration with a Chinese company, Xiajiang Farm-149, Pakistan's Agricultural Research Center (PARC) has imported one ton of Bt cottonseed from China. The seed has been planted in 25 acre plots at eight locations in Sindh and

Punjab. Eight Chinese experts are reportedly working at the test sites. While these trials of Chinese seed appear to be in clear violation of Pakistan's existing national biosafety rules and obligations, the project is expected to have a five-year timeline and will include other biotech crops such as rice, sugarcane, bananas, vegetables and wheat.

Treatment of Stacked Events

The National Biosafety Committee (NBC) considers each event as a separate case and would consider combined "stacked events" as a unique event.

The NBC has approved the stacked genes Cry 1A and Cry 2Ab0 for cotton developed by CEMB in Lahore. Several other stacked gene events are in the pipeline towards approval.

Product Registration

Pakistan's system of biotech product registration and approval is chaotic and slow.

In addition to the original approval system noted in the "Regulatory Framework" section, there remains biosafety approval from NBC and SOPs from MinFA. Both public institutes and private sector companies are struggling to navigate through the system to obtain commercial approval and import permits for biotech seed.

Policy on Coexistence

At present, the GOP has not formulated a policy on coexistence between biotech and non-biotech crops.

Labeling of Packaged Foods or Feed

The GOP does not require labeling of packaged food or feed originating from GM crops. GM derived edible oil and food is imported without any restrictions. Facilities are available for the testing of GM content of imports and exports.

Biosafety Protocol

Pakistan ratified the Cartagena Protocol on Biosafety (CPB) on May 31, 2009.

However, the GOP's capacity to implement the Protocol is low. The National Biosafety Directorate is not a permanent body and faces chronic funding and personnel shortfalls. The widespread cultivation of non-approved Bt cotton and the blatant planting of new unapproved Chinese Bt cotton varieties are indications of the impotency of the NBC.

Biotechnology-Related Barriers to Trade

To date, Pakistan has not approved any biotech seed for domestic cultivation. However, there are no laws banning the import of biotech cotton for further processing, biotech oilseeds and meal, biotech feed corn, soybean or other edible oil derived from biotech oilseeds or products containing such oil.

IPR Rights for Biotech Crops

Multinational seed companies and local private companies are anxious to see the pending biotech-related IPR legislation passed in order to protect any future investment in infrastructure or seed development.

Section V. Marketing: Market Acceptance of Biotech Products

Industry and consumers currently accept GM soybeans, soybean meal, soy oil and other processed food products without opposition. NGO's have raised their voices against agricultural biotechnology with minimal impact on the public debate.

Pakistan's agricultural community advocates the utilization of GM technology to increase productivity. As evidence, over 90 percent of the 2009/10 cotton crop is considered planted to illegal/unapproved Bt cotton varieties.

Section VI. Capacity Building and Outreach:

Recent U.S. Government or USDA-funded Activities

The U.S. Government has funded the following capacity building and outreach projects in Pakistan related to agricultural biotechnology.

- Biotechnology is considered an important area for funding under trilateral collaboration among the United States, Pakistan and Afghanistan. A Pakistani delegation headed by the Minister of Agriculture visited Washington D.C in May 2009 to discuss broad areas of collaboration, including biotechnology, under the Trilateral Agreement.
- A regional symposium on wheat stem rust convened on August 12-13, 2009 at the National Agriculture Research Center (NARC) in Islamabad. The symposium was jointly sponsored by NARC, USDA and State Department's Bioengagement Program.
- Two Cochran Fellowship Program teams will travel to the United States for training in August-September 2009. The seed technology team and a dairy genetics team will each have about six fellows participating.
- Two scientists will receive training at CIMMYT Mexico in management of wheat stem rust under the 2009 Borlaug Program.
- A Tripartite Meeting on Agricultural Biotechnology (United States, India and Pakistan) was held on May 24-25, 2005 in Lahore, Pakistan with funding from USAID.
- Under a 2003 PL-480 Food for Progress grant with USDA, the University of Agriculture Faisalabad will receive and disburse \$50,000 per year to fund Borlaug Fellows to conduct research on issues of agricultural biotechnology.
- Post-doctoral research on biotechnology and related agricultural issues will be funded under a Young Scientists Program, as part of the USDA-funded sustainable endowment to support the Agricultural Linkages Program at the Pakistan Agricultural Research Council.
- USAID-funded biotechnology training of fifteen scientists under the Management of Agricultural Research and Training (MART) program.
- An MOU for \$7.5 million has been signed under the Pakistan-U.S. Science and Technology Program between Pakistan's Higher Education Commission (HEC) and the Ministry of Science and Technology and the U.S. Agricultural Research Service (ARS) for scientific collaboration and capacity building of scientists.
- A USG delegation visited Pakistan on March 15-21, 2007 to discuss issues of biosafety, biosecurity and overlapping areas with scientists and officials.
- A Pak-U.S. Project USNAS with the Higher Education Commission and Ministry of Science and Technology covers 3-5 projects on GM crop development.
- Agricultural Linkages Program at the Pakistan Agriculture Research Council, Islamabad and Faculty Development, Technology Transfer and Product Commercialization (FDTTPC) funding to University of

Agriculture, Faisalabad – ongoing activity to fund projects on biotechnology for crop and livestock improvement.

- The Deputy Administrator of USDA's Agricultural Research Service visited Pakistan in October 2007 under the Science and Technology Agreement to further U.S.-Pakistan agricultural research collaboration in areas including agricultural biotechnology.

Areas for Potential Future Capacity Building Efforts

- Pakistan is looking to build the capacity of its young scientists in the legislative, regulatory, and policy areas related to agricultural biotechnology, biosafety and nanotechnology.
- Other areas for future biotechnology collaboration include capacity building at all levels -- with the National Biosafety Directorate at the Ministry of Environment, the Federal Seed Certification and Registration Department at MINFA, specialists at Pakistan's National Animal and Plant Health Inspection Service, and scientists involved in biotechnology applications for crops and livestock.

SECTION VI: ANIMAL BIOTECHNOLOGY

Development and Use

No genetic engineering of livestock has been initiated in Pakistan.

Livestock improvement programs are limited to genomic diagnoses for gene identification, reproductive biotechnology for artificial insemination and embryo transfer and cell culture for producing prophylactic vaccines, pharmaceutical proteins and monoclonal antibodies. Practical applications include molecular diagnostic testing for avian influenza and foot and mouth disease.

Recently two important initiatives with USDA technical support have begun at the University of Veterinary and Animal Sciences (UVAS) in Lahore and the National Institute for Genomics and Advanced Biotechnology (NIGAB) at NARC in Islamabad in animal genomics of cattle.

Another project with the support of ILLRI on sheep and goats genomics has been initiated with EU funds.

Regulation

No separate regulations or legislation exists related to animal biotechnology in Pakistan.

The National Biosafety Committee (NBC) is responsible for biosafety issue related to all areas of biotechnology - including animals and their products.

Stakeholders/Public Opinions

There are no active organizations or public campaigns that lobby in Pakistan either for or against the genetic engineering of agriculturally-relevant animals.

International Organizations

Pakistan does not actively participate in discussions related to genetic engineering of agriculturally-relevant animals in international organizations.

Outreach, Needs and Strategies

The genetic engineering of agriculturally-relevant animals is not yet developed in Pakistan.